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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/718,770	DUNLAY ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-18 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02012006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 2/1/06, are acknowledged. Amended claims 13, 18, and 24-25 and cancelled claims 19-22 are acknowledged.

Applicant's arguments, filed 2/1/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The information disclosure statement (IDS) submitted on 2/1/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claims 13-18 and 23-25 are herein under examination.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER

Applicant points to support for "subcellular" limitation in amended claim 13 on page 13 (lines 22-24), Figure 7, examples on page 12 (lines 1-31), Examples 1 and 2, and page 19 (lines 1-17). It is noted that written support is provided for the image analysis of two particular sub-cellular components, the nucleus and cytoplasm, but not for "subcellular" image data in general, which is broader in scope. Because the introduction of "subcellular" does not appear to have adequate written support in the specification, claims, and/or drawings, as originally filed, this term is considered to be NEW MATTER. Claims 14-18 and 23-25 are also rejected due to their dependency from instant claim 13. This rejection is necessitated by amendment.

Several limitations in instant claims 24 and 25 do not appear to have written support in the specification, claims, and/or drawings as originally filed: "perimeter", "height", "width", "ratio of fluorescent intensities", and "difference in fluorescent intensities". On page 12, line 4, written support is provided for "perimeter squared area", but not for "perimeter" which is broader in scope. On page 12, line 6, written support is provided for "height width ratio", but not for individual concepts of "height" and "width" which are broader in scope. On page 12, lines 14-15, written support is provided for "the ratio of the average fluorescent intensity of the cytoplasmic mask to the average fluorescent intensity within the cell nucleus for colors 2-4", but not for "ratio of fluorescent intensities" which is broader in scope. On page 12, lines 16-17, written support is provided for "the difference of the average fluorescent intensity of the cytoplasmic mask and the average fluorescent intensity within the cell nucleus for colors 2-4", but not for "differences in fluorescent intensities" which is broader in scope. Because the introduction of these limitations do not appear to have written support in the specification,

claims, and/or drawings as originally filed, they are considered to be NEW MATTER. This rejection is maintained.

Applicants argue that one of skill in the art would understand that determining "perimeter squared area" includes determining "perimeter". This statement is found unpersuasive as one skilled in the art could collect a perimeter squared area from the image data which does not necessarily include collecting the individual "perimeter" measurement from the image data which is broader in scope.

Applicants argue that one of skill in the art would understand that determining "height width ratio" includes determining "height". This statement is found unpersuasive as one skilled in the art could collect a height width ratio from the image data which does not necessarily include collecting the individual "height" measurement from the image data which is broader in scope.

Applicants argue that one of skill in the art would understand that determining "height width ratio" includes determining "width". This statement is found unpersuasive as one skilled in the art could collect a height width ratio from the image data which does not necessarily include collecting the individual "width" measurement from the image data which is broader in scope.

Applicants argue that the specification clearly provides explicit examples of using ratios of fluorescent intensities in the cytoplasm-nucleus translocation assays and translocation between cytoplasm and plasma membrane assays, including page 19, lines 3-15, of the specification. Applicants argue that it would therefore be clear to those of skill in the art that Applicants had

possession of other translocation assays and that the ratios could be used in these other translocation assays. This statement is found unpersuasive as the written support in the specification focuses on the ratio of average fluorescent intensities which differs in scope. Applicants argue that the previous office action was incorrect because it stated that "Applicants cite several passages on pages 12 and 19, but these passages fail to mention ratios". This statement is confusing as these pages do not mention ratios which is part of the limitation for which Applicants are arguing written support. It is acknowledged that written support is provided for "the ratio of the average fluorescent intensity of the cytoplasmic mask to the average fluorescent intensity within the cell nucleus for colors 2-4" (page 12, lines 14-15). The section on page 19, lines 3-15, of the specification does not provide adequate written support for "ratio of fluorescent intensities" as there is no mention of "ratios". Furthermore, the rejected limitation "ratio of fluorescent intensities" is broad and encompasses intensities which are not supported by the original disclosure.

Applicants argue that the specification clearly provides explicit examples of using differences in fluorescent intensities in the cytoplasm-nucleus translocation assays and translocation between cytoplasm and plasma membrane assays, including page 19, lines 3-15, of the specification. Applicants argue that it would therefore be clear to those of skill in the art that Applicants had possession of other translocation assays and that the differences could be used in these other translocation assays. This statement is found unpersuasive as the written support in the specification focuses on the difference of average fluorescent intensities which differs in scope. Applicants argue that those skilled in the art would recognize a wide variety of distinct screens that can be developed which includes the determination of differences in fluorescent

intensities between organelles. It is noted that the limitation "difference in fluorescent intensities" encompasses more than just intensities between organelles, such as other entities, which do not have adequate written support.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-18 and 23-25 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Nova et al. (P/N 5,961,923).

This rejection is maintained.

Nova et al. disclose a method involving cell sorting assays, storage of matrices with memories on machine-readable media, and retrieving stored information (abstract) as recited in the preamble of instant claim 13. Nova et al. disclose the use of high throughput screening on microplate formats to screen a number of drug compounds and cell-based assays (col. 6, lines 7-19) which represents providing a microplate comprising cells and treating with a test compound,

(as stated in instant claims 13, 15, and 16) wherein the matrices which are microplates containing 96, 384, or higher format wells with each well or selected wells including a memory device (col. 8, lines 30-36 and lines 63-67) as stated in step a) of instant claim 13. Nova et al. disclose computer systems and methods for recording, reading, or retrieving information in the data storage devices (col. 15 lines 60-67) which represent the computer system of instant claim 13. Nova et al. disclose maintaining a database that includes all patient information for the sample as well as other aspects of the patient's file (col. 83, lines 9-20) which represents the computer system database, as stated in instant claim 13. Nova et al. disclose using memory devices that include the input/output of stored information for higher density memories (col. 13, lines 49-56) and software allowing the user to specify what chemical blocks are to be used, the number of steps, and pharmacophore names (col. 87, lines 39-51) as well as using user-entered compound names stored in a database (col. 88, lines 17-20) which represent storing input parameters used for screening in a database, as stated in step b) of instant claim 13 as well as software having instructions causing a computer to execute a method, as stated in instant claim 14. Nova et al. disclose individual particles can be identified by reserving certain memory locations for identification only, individual identification (col. 73, lines 1-11), as well as software providing archival capability for a 96-well format where individual wells can be selected (col. 88, lines 48-54) which represents selecting an individual well on the plate and storing information, as stated in step c)i) of instant claim 13 and microplate data, as stated in instant claim 17. Nova et al. disclose software reading one tag and encoded information including graphical displays, reports including progress (calculations) (col. 88, lines 16-34), searching for specific compounds with certain building blocks (feature data) including those already archived by displaying structure,

archive location, microplate group name, number and well (col. 88, lines 55-62 and Figure 6), using fluorophors or other luminescent moieties, labeling molecules and biological particles, tagging molecules (abstract), tagging molecules such as antigens, antibodies, ligands, proteins, and nucleic acids and tagging by imprinting the matrix with identifying information (col. 4, lines 58-67 and col. 7, lines 6-15), using optical memories that rely on changes in chemical or physical properties of molecules and storing information associated with each matrix including reaction detection (col. 7, lines 16-32 and lines 57-67), a photodetector to detect fluorescent occurrence or other optical emission (col. 10, lines 6-23), and using bar codes associated with each well in a microtiter plate (col. 8, lines 60-67) which represents collecting, calculating, storing, and retrieving subcellular image data, cell feature data, well summary data, plate summary data in a database, as stated in steps i) through ix) of instant claim 13 as well as instant claim 17. Nova et al. disclose optical memory devices (OMD) and image acquisition from a camera that can be displayed to the system monitor including edges and peak signals as well as determining the average intensity of each cell (col. 9, line 18; col. 51, line 61 to col. 52, line 9 and lines 27-60; and Figure 31) which represents collecting image data, intensity analysis, and feature data of cells, as stated in instant claims 13 and 23-25. Nova et al. disclose repeating the steps for handling, writing, reading, and distributing the optical memory devices to the next process step (col. 54, lines 5-11 and Figure 18) which represents the repeating steps in step c) of instant claim 13. Nova et al. disclose other repeating screening protocols (col. 118, lines 35-36 and 54-57 and col. 128, lines 39-49). Nova et al. disclose recording devices including a photodetector to detect the occurrence of fluorescence or other optical emission and permitting data storage (col. 10,

lines 6-23) which represents a computer system database that includes photographic image data, as stated in instant claim 18.

Thus, Nova et al. anticipate the instant invention.

Applicants argue that Nova et al. do not teach collecting image data from the cells in the wells or any further steps involving image data. This statement is found unpersuasive as the labeled biomolecules detected by the photodetector (abstract and col. 10, lines 6-23) as well as the repetitive steps of Figure 18 represent collecting subcellular image data and further processing steps. Applicants argue that col. 51 (line 61) to col. 52 (line 9) teach generating a snapshot of the optical memory surface which does not refer to generating image data from cells in wells. It is noted that Nova et al. disclose cell-based assays using bar codes associated with each well in a microtiter plate (col. 6, line 18 and col. 8, lines 60-67) as well as recording fluorescent and other optical emissions (col. 10, lines 13-15) which represents generating image data from cells in wells. Applicants argue that Nova et al. do not teach collecting subcellular image data from cells in wells. This statement is found unpersuasive as Nova et al. disclose using fluorophors or other luminescent moieties, labeling molecules and biological particles, tagging molecules (abstract), tagging molecules such as antigens, antibodies, ligands, proteins, and nucleic acids and tagging by imprinting the matrix with identifying information (col. 4, lines 58-67 and col. 7, lines 6-15), using optical memories that rely on changes in chemical or physical properties of molecules and storing information associated with each matrix including reaction detection (col. 7, lines 16-32 and lines 57-67), a photodetector to detect fluorescent occurrence or other optical emission (col. 10, lines 6-23).

Applicants' arguments are deemed unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
4/4/06

April 3, 2006